REMARKS

Please cancel claims 18-31, which claims have been restricted out and withdrawn from the prosecution of the present application by the Examiner. Applicants expressly retain all rights in the cancelled claims for further consideration, as they deem appropriate. The cancellation of these claims should in no manner whatsoever be construed as a dedication of the subject matter of these claims to the public.

It is noted that the previous rejections of claims 1-17, 32, 34, and 35; and claim 33 in the Official Action dated April 16, 2004 have been withdrawn in view of amended claim 1 in the previous Response.

No claims are amended in response to the present Official Action, other than the cancellation of the withdrawn claims above.

In view of the following remarks in response to the Official Action, favorable reconsideration is respectfully requested. It is submitted that the Response places the Application in condition for allowance. Alternatively, the Examiner is kindly requested to enter the Response into the record, which Response narrows the issues for disposition on Appeal. Entry of the Response is therefore kindly solicited.

Rejections under 35 USC 103(a)

Claims 1-9, 11-14 and 17 are newly rejected under 35 USC 103(a) as being unpatentable over Cook in view of Fowler and further in view of newly cited US Pat. No. 5,752,934 ("Campbell").

The rejection of the claims is respectfully traversed. For the reasons discussed hereinafter, it is respectfully submitted that claims 1-9, 11-14 and 17 are patentable over the prior art. Further, it is respectfully submitted that claims 1-17 and 32-35 are patentable over the prior art.

Cook (the 1° reference) and Fowler (the 2° reference) have previously been and continue to be the basis for all of the rejections of the claims. Campbell is now newly cited (as a 3° reference) by the Examiner for its teachings, *inter alia*, of "a complete balloon or as a cover for catheter balloons...one of skill in the art would have recognized to have used the balloon composite material taught by Cook and Fowler et al. as the material of a balloon catheter cover such as the balloon catheter cover of Campbell et al...(emphasis added)."

Hence, this rejection, as well as all of the other rejections in the Official Action, is based on the combination of Cook and Fowler for their teachings of "balloon composite material", as such material is construed by the Examiner.

The arguments for the patentability of the claims submitted previously are neither withdrawn nor abandoned. Applicants also submit the following additional arguments in support of patentability.

According to the Examiner, "[t]he Office acknowledges that Cook fails to teach that the fabric structure is of interconnected circumferential and longitudinal yarns in the 35 U.S.C. 103(a) rejection of claim 1; this structure is taught by Fowler et al. ... (emphasis added)." According to the Examiner then, "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the elastic fabric structure of Cook with

the elastic fabric structure of interconnected circumferential and longitudinal yarns of Fowler...(emphasis added)."

The issue then is whether, under the law, the Examiner's proposed "replacement" of the fabric structure of Fowler for the fabric structure of Cook is an appropriate and permissible basis to reject the claims of the present invention under Section 103(a).

For the following reasons, it is respectfully submitted that the Examiner's "combination" of Cook and Fowler in such fashion as to "replace" the fabric structure of Cook with the fabric structure of Fowler is legally improper and would constitute reversible error in a legal proceeding.

The Examiner's attention is directed to MPEP 2143.01 entitled "THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE."

According to MPEP 2143.01:

> "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) ... The court reversed the rejection holding the 'suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate...(emphasis added)"

With respect to the present invention and the rejection of the claims over Cook in view of Fowler, it is respectfully submitted that the substitution of the fiber construction of Fowler would require a substantial reconstruction and redesign of the elements shown in Cook as well as a change in the basic

principle under which the Cook construction was designed to operate, pursuant to MPEP 2143.01 and the holding in *In re Ratti* cited therein.

According to the disclosure of Cook, the balloon catheter is reinforced with a knitted fabric layer to limit the maximum expanded diameter of the balloon. Col.1, lls 48-52. It is an object of Cook to provide an improved balloon catheter which is reinforced to limit its maximum expanded diameter, yet which has a smooth configuration in both its contracted and expanded states. Col. 1, lls. 53-57.

At Col. 2, lls. 57-62 through Col. 3, lls 1-16, Cook references FIG.4 and discloses that "there is shown in detail the configuration of a portion of knitted middle layer **23** in an expanded state. Middle layer **23** is knitted as a tube from a single yarn strand arranged generally in a helix, with each turn of the helix comprising a successive row of knitting ... [a]s is characteristic of knitted fabric, each row is configured as a series of periodically spaced loops, with each loop in each row passing through an adjacent loop in the next preceding row. To illustrate this knit stitch, one row **35** in FIG. **4** is shown darker. Row **35** includes a series of loops such as loops **36**, **37**, and **38**, each of which passes through loops **36'**, **37'**, and **38'**, respectively, of the next preceding row.

The yarn strand **39** of which middle layer **23** is knitted is comprised of multiple [meaning 2 or more] plies or filaments. In the preferred embodiment [of multiple plies or filaments], the yarn strand is comprised of two parallel twisted plies, one ply **39A** being strong and inelastic for limiting the maximum expanded diameter of the balloon, and the other ply **39B** being elastic for

contracting the balloon when inflation pressure is absent", which is in accordance with the objects of Cook stated above (emphasis added).

Cook thus teaches a middle layer 23 comprised of a single yarn of multiple plies or filaments of elastic and inelastic fibers oriented solely in the parallel direction. The preferred embodiment of "multiple plies" is explicitly taught as "two parallel twisted plies."

In the Official Action of April 16, 2004, at page 8, the Examiner stated that: "[A]pplicant argues that there is no motivation to combine the references since 'Cook requires that the elastomer and hard fibers be parallel to each other', but this is not the case; the condition that the elastomer and hard fibers be parallel to each other is preferred ... (emphasis added)."

The Examiner is incorrect in his interpretation of Cook as it relates to its "preferred" teaching. Cook only describes elastic and inelastic fibers oriented in the parallel direction. Also see claims 3 and 11 of Cook, which claims call for a "plurality of parallel plies, at least one of said plies being elastic and at least one of said plies being strong and inelastic (emphasis added)."

If Cook teaches anything else as "the case", then the Examiner is kindly requested to so indicate. Cook certainly does not teach such fibers oriented in a perpendicular direction (circumferential and longitudinal). The Examiner has already so admitted on the record that "Cook fails to teach that the fabric structure is of interconnected circumferential and longitudinal yarns...", so his positions in this regard are inconsistent and irreconcilable.

Thus, the construction of the knitted fabric of Cook for use in an inflatable catheter balloon is a tube construction knitted from a single yarn in a

helical structure, with both the elastic and inelastic plies (no matter the number of plies) situated in the parallel direction (as clearly described above and illustrated in 39A and 39B of FIG.4 of Cook).

At. Col.3, lls. 46-55, Cook describes the advantages of this specific knitted construction over "prior known fabric reinforced balloons."

The construction of Cook is distinctly different from the construction of Fowler, as admitted on the record by the Examiner. With this admission, the Applicants are in complete agreement with the Examiner.

Fowler describes at Col. 2, lls 65-68 and shows at FIG. 2 that there are 2 yarns, (elastic yarn 18 and inelastic yarn 16 of FIG 2), as compared with the single yarn of Cook, as discussed above. In addition, the 2 yarns of Fowler are oriented in the perpendicular direction with respect to each other, as compared to the parallel orientation of the elastic and inelastic yarns of Cook.

Comparing FIG. 4 of Cook with FIGS. 2-7 of Fowler, it is clearly apparent that the fabric constructions of Cook and Fowler are dramatically different and distinct from each other.

To replace the construction of Cook with that of Fowler, as proposed by the Examiner would require an extensive reconstruction and redesign of the elements shown in Cook as well as a change in the basic principle under which the Cook construction was designed to operate.

Pursuant to the holding in *In re Ratti*, the Examiner's proposed "replacement" of the fabric construction of Cook with the fabric construction of Fowler is clearly impermissible under the law, and hence "the teachings of the references are not sufficient to render the claims *prima facie* obvious."

According to the Examiner, Cook and Fowler "constitute analogous art because both patents teach a cylindrical fabric structure that perform [sic] an equivalent mechanical function." Applicants' objection to the proposition that Fowler and Cook are analogous art has been previously stated on the record and will not be repeated here.

Assuming however, just for the sake of the following discussion, that Cook and Fowler are "analogous art", as stated by the Examiner, it is worth noting that Fowler predates the invention of Cook by several years. So if Fowler were "analogous art", it is reasonable to conclude that Cook, at the time of his invention, would have considered fabric structures of the type taught by Fowler (2 separate yarns of elastic and inelastic fibers oriented in a perpendicular direction with respect to each other) for solving the problems with respect to the fabric structure of prior art balloon catheters. Since Cook opted for a single yarn constituted of both elastic and inelastic fibers in a parallel orientation to address the shortcomings of the prior art, it would then be reasonable to presume that Cook clearly rejected the prior art teachings of 2 separate yarns of elastic and inelastic fibers in perpendicular orientation, as taught by Fowler, as suitable to resolving the problems with the fabric structures of balloon catheters. Such a presumption would be reasonable since Cook opted for a completely different and distinct fabric structure than that taught by Fowler, as discussed at length above.

In Summary, the teachings of Cook, as the primary reference here, clearly would lead one of skill in the art away from the claimed invention. The Examiner's proposed replacement of the fabric structure of Fowler for that of Cook as the basis for a 103(a) rejection would require a substantial

reconstruction and redesign of the elements shown in Cook as well as a change in the basic principle under which the Cook construction was designed to operate. As discussed above, such an extensive modification of Cook is improper under the law and cannot serve as a basis for a rejection under 35 USC 103(a).

It is therefore respectfully submitted that claims 1-9, 11-14 and 17 are patentable over the prior art. The Examiner is kindly requested to reconsider and withdraw the rejection.

It is also respectfully submitted that claims 10, 15, 16, and 32-35 are patentable over the prior art rejections at Paragraphs 6-9 of the Official Action for the reasons discussed above with respect to the rejection of claims 1-9, 11-14, and 17.

Applicants therefore respectfully submit that claims 1-17 and 18-31 are patentable over the prior art.

Favorable reconsideration is respectfully solicited. Entry of the Response, which places the application in condition for allowance, is respectfully requested. Alternatively, the Examiner is requested to enter the Response for purposes of Appeal. Should the Examiner believe that an interview or other action in Applicants' behalf would expedite prosecution of the application, the Examiner is urged to contact Applicants' attorney by telephone at (302) 992-3219.

Respectfully submitted,

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Dated: February 2/24/05